12-Person Jury

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IRIS Y. MARTINEZ
CIRCUIT CLERK
COOK COUNTY, IL
16458002

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

ELLEN BEASLEY,	:
Plaintiff,	: Cause No. 2022L000833
v.	: Hearing Date: 3/29/2022 10:00 AM
ACTAVIS LLC f/k/a ACTAVIS INC., ACTAVIS PHARMA, INC., AND SAGENT PHARMACEUTICALS INC.,	: **Plaintiff Demands a Trial by Jury**
Defendants.	:

COMPLAINT AT LAW

NOW COMES Plaintiff ELLEN BEASLEY, by and through her attorneys, Kelleher + Holland, LLC, and for her Complaint against defendants Actavis LLC f/k/a Actavis Inc., Actavis Pharma, Inc. and Sagent Pharmaceuticals Inc. (collectively "Defendants"), alleges as follows:

PARTIES

A. Plaintiff

1. Plaintiff is an individual residing in Southside, Alabama who received Docetaxel Injection as part of a weekly chemotherapy regimen after being diagnosed with breast cancer at Hematology & Oncology Associates of Alabama in Gadsden, Alabama.

B. Defendants

2. Defendant Actavis LLC f/k/a Actavis Inc. is a pharmaceutical limited liability

company organized and existing under the laws of the State of Delaware with a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Defendant Actavis Pharma Inc. is a pharmaceutical company organized and existing under the laws of State of Delaware with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. In 2016, Teva Pharmaceuticals, Ltd. Acquired Defendant Actavis Pharma Inc. Prior to 2016, Actavis Pharma Inc. was a wholly owned subsidiary of Defendant Actavis LLC f/k/a Actavis Inc.

4. Defendant Sagent Pharmaceuticals, Inc. ("Sagent") is incorporated under the laws of Delaware and maintains its principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, Illinois 60195.

5. Defendants transacted and conducted business throughout the United States and in the state of Illinois.

6. Defendants derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold and distributed throughout the United States.

7. At all relevant times, Defendants were in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #203551.

8. The proprietary name for Defendants' branded drug is Docetaxel Injection

Concentrate.

9. Defendants expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

10. Defendant Actavis filed NDA #203551 on March 14, 2012 under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act. Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere. Sagent also sold this product (NDCs: 25021-222-01, 25021-222-04, and 25021-222-07) manufactured by Actavis under Actavis' NDA

11. Defendants one-vial formulation, however, was different from Taxotere's one-vial formulation because it is offered at an additional 140 mg dosage form, contains excipients citric acid and Kollidor 12 PF (Povidone k12), and uses reduced levels of polysorbate 80. After Actavis' initial Docetaxel Injection approval, a 160 mg dosage form was also introduced.

JURISDICTION AND VENUE

12. As a citizen of Illinois, Defendant Sagent is subject to personal jurisdiction in this Court, and venue is proper here under 735 ILCS 5/2-101. This case is not removable to federal court because Plaintiff sues Sagent in its home state.

13. Defendants Actavis LLC and Actavis Pharma, Inc. regularly conduct business in the state and are subject to its jurisdiction.

14. Because venue is proper as to Sagent, venue is proper for all Defendants under the

rules of permissive joinder.

FACTUAL ALLEGATIONS

I. Development and Approval of Docetaxel Injection

15. Taxotere and Docetaxel Injection are drugs used in the treatment of various forms of cancer, including breast cancer, and are a part of a family of cytoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and unlike other cytoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell reproduction. They are widely used as chemotherapy agents.

16. The FDA first approved Taxotere on May 14, 1996 for limited use—namely, for the treatment of patients with locally advanced or metastatic breast cancer that had either (1) progressed during anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

17. In August, 2004, the manufacturer of Taxotere obtained FDA approval for an expanded use of the drug "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

18. As the universe of patients taking Taxotere expanded to include patients with a higher survivability rate, more cancer survivors taking Taxotere would now experience a permanent disabling (but preventable) condition—namely, permanent damage to the

lacrimal system.

19. On March 14, 2012, Actavis filed NDA application #203551 to market its Docetaxel Injection under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"), codified at §21 U.S.C. 355(b)(2).

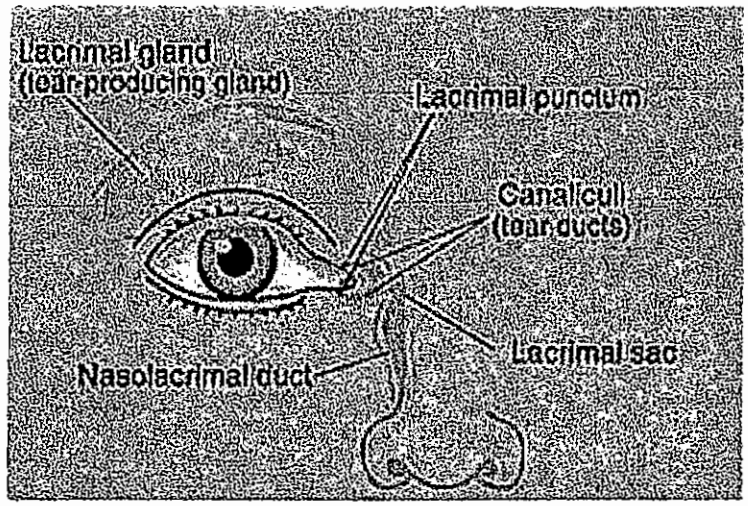
20. Actavis received FDA approval for NDA #203551 on April 12, 2013 and began marketing these dosage forms on July 1, 2013.

21. Since approval, Actavis has submitted multiple Changes Being Effected Supplemental New Drug Applications ("CBE sNDA") to update its labeling. It submitted a CBE sNDA (S-001) on May 14, 2013, which was approved on November 4, 2013. It also submitted a "Prior Approval" sNDA (S-002) on March 21, 2014, which was approved on September 17, 2014. Neither submission, however, updated its labeling concerning **permanent** damage to the lacrimal system.

22. Docetaxel Injection is not purchased by patients at a pharmacy; rather, patients' use of this drug occurs via administration through injection and/or intravenously at a physician's office or medical treatment facility.

II. Anatomy of Lacrimal System

23. The following image depicts the anatomy of the lacrimal system.



24. Docetaxel Injection is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system, including the lacrimal punctum, canaliculi and/or nasolacrimal duct. This scarring can cause permanent occlusion, causing an inability for tears to drain naturally through the lacrimal system. Because the eyes are constantly producing tears, this results in persistent epiphora.

III. Docetaxel Injection's Labeling

25. At the time Plaintiff was administered Docetaxel Injection Concentrate, its labeling stated in relevant part under **Post-Marketing Experiences:**

> **Ophthalmologic:** conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive tearing which may be attributable to lacrimal duct obstruction has been reported. Rare cases of transient visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions have been reported. These were reversible upon discontinuation of the infusion.

and under **Patient Counseling Information:**[1]

> • Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, excessive tearing, infusion site reactions, and hair loss are associated with docetaxel administration.

26. Additionally, in the *Patient Information* section of the label, Defendants include "redness of the eye, excess tearing" among "the most common side effects of Docetaxel Injection." *Id.* Defendants' inclusion of this potentially permanent side effect in a laundry list of common, *but notably transitory*, side effects effectively misrepresents the risk of harm associated with tearing. By failing to fully inform patients and physicians of the potential for serious permanent damage to the lacrimal system, Defendants downplay the significance of the underlying injury causing epiphora.

27. Defendants' labeling information at all times relevant to this lawsuit, and even to date, does not identify the risk of stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur, the potentially permanent nature of the injury, the need to refer patients to a lacrimal specialist, nor does it identify the condition as preventable with timely intervention during chemotherapy.

28. Defendants did not provide such adequate notice to oncologists. To the contrary, the labeling leads oncologists, like Plaintiff's, to believe that excessive tearing is merely a transitory side effect and will end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of women, like Plaintiff, suffering daily from a

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/203551s001lbl.pdf

permanent condition that could have easily been prevented with adequate warning.

IV. Defendants' Duty to Monitor and Update Labeling

29. The primary responsibility for timely communicating complete, accurate, and current safety and efficacy information related to Docetaxel Injection rests with Defendants because they have superior, and in many cases exclusive access to the relevant safety and efficacy information, including post-market complaints and data.

30. To fulfill its essential responsibilities, Defendants must vigilantly monitor all reasonably available information. It must closely evaluate the post-market clinical experience of its drugs and timely provide updated safety and efficacy information to the healthcare community and to consumers.

31. When monitoring and reporting adverse events, as required by both federal regulations and state law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to drug sponsors and the medical community that a public safety problem exists.

32. If, for example, a manufacturer was to delay reporting post-market information, that delay could mean that researchers, FDA, and the medical community are years behind in identifying a public safety issue associated with the drug.

33. In the meantime, more patients are harmed by using the product without knowing, understanding, and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor, investigate and report post-market

experiences, but must also report the data in a timely fashion.

34. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading or does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists sufficient information—including indications for use and "any relevant hazards, contraindications, side effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

35. As part of their responsibility to monitor post-market clinical experiences with the drug and provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b).

36. Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii).

37. Most other adverse event reports must be submitted quarterly for three years after

the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(ii).

38. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

39. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. § 314.70.

40. One regulation, the "Changes Being Effected" (CBE) regulation, permits a manufacturer to unilaterally change a drug label to reflect "newly acquired information," subject to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes "new analyses of previously submitted data." 21 C.F.R. § 314.3(b).

41. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new analysis of previously existing data, it could submit a CBE and change its

labeling.

42. The longer a drug sponsor delays updating its labeling to reflect current safety information, the more likely it is that medical professionals will prescribe the drug without advising patients of harmful adverse reactions, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

V. Defendants Knew That Docetaxel Injection Can Cause Permanent Nasolacrimal Duct Obstruction

43. After Defendants submitted their NDA for approval to the FDA, accumulating data demonstrated that the warning advising of "lacrimal duct obstruction" failed to adequately communicate to oncologists the severity and permanency of Docetaxel Injection-related epiphora. This accumulating data highlighted concerns of the increased frequency and severity of docetaxel-induced permanent stenosis in cancer patients, the increased need for monitoring, and the lack of awareness among oncologists and their patients regarding the true nature of the damage caused. The following excerpts are just a sampling of the accumulating data:

- The second most common adverse event [of docetaxel administration] was watery eyes and tearing (epiphora), affecting 55 patients (50.9%) in the one week group… this side effect was very specific for the weekly regimen and the frequency increased for every

consecutive treatment cycle.[2]

- In conclusion, it is important for oncologists to be aware of this adverse event, and ophthalmologists should be consulted in cases in which tears appear during docetaxel therapy.[3]

44. Following the approval of Defendants' NDA, published studies highlighted an ongoing problem that oncologists did not appreciate the seriousness of potential **permanent** damage to the lacrimal system as a result of Docetaxel Injection. Despite the prevalence of accumulating data, Defendants took no efforts to analyze this data and take measures to add a stronger warning to the oncological community.

45. Defendants' decision to willfully ignore this data resulted in an increase of cases of permanent injuries to the end users of its product.

46. Defendants had ample opportunity to utilize the CBE process and unilaterally strengthen its label to raise awareness among oncologists as recommended by the studies. Of note, in 2018 Defendants utilized the CBE process to change their warning label regarding the side effects of alopecia. Specifically, Defendants sought to strengthen the warning to include the word "**permanent**" with regard to alopecia.

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[2] Sorbe, Bengt, et al., *A Study of Docetaxel Weekly or Every Three Weeks in Combination with Carboplatin as First Line Chemotherapy in Epithelial Ovarian Cancer: Hematological and Non-Hematological Toxicity Profiles*, 5(4) ONCOLOGY LETTERS 1140-1148 (2013).

[3] Yamagishi, T., Ochi, N., Yamane, H. et al. *Epiphora in Lung Cancer Patients Receiving Docetaxel: A Case Series*, 7 BMC RES NOTES 322 (2014).

47. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon initiation of Docetaxel Injection administration; (2) immediate referral to a lacrimal specialist for monitoring is essential; (3) damage to the lacrimal system can be permanent; (4) this side effect is preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness often results in oncologists counseling their patients that their tearing is a temporary side effect and will eventually subside.

VI. Docetaxel Injection Caused Plaintiff's Permanent Nasolacrimal Duct Obstruction

48. Plaintiff was diagnosed with breast cancer and was initially given chemotherapy with Defendants' Docetaxel Injection. However, during her ten rounds of Docetaxel Injection, she developed tearing and exhaustion and was switched to Taxol for her final two chemotherapy treatments.

49. Plaintiff completed chemotherapy and was excited to be cancer free and rid of all of the side effects she suffered as a result of the cancer treatment. Among these, Plaintiff looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off, the epiphora continued; however Plaintiff remained hopeful that it would eventually resolve. To her dismay, it never has.

50. Plaintiff continues to experience persistent tearing and a disruption of life. As a direct and proximate result of Defendants' conduct in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing,

distribution, labeling, warning, and sale of Docetaxel Injection, Plaintiff suffers from epiphora due to permanent nasolacrimal duct obstruction. This condition is a known permanent side effect of taking Docetaxel Injection concentrate.

51. As a result of this permanent side effect, Plaintiff has struggled to return to normalcy even after surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering with her ability to perform basic activities and enjoy life. This permanent change has altered Plaintiff's self-image, negatively impacted her relationships, and others' perceptions of her, leading to social isolation and depression even long after fighting cancer.

52. Plaintiff's tearing impacts all aspects of her daily life. Prior to developing permanent nasolacrimal duct obstruction, Plaintiff was self-confident and enjoyed social interactions with other people. Now she lacks the confidence she previously enjoyed. Plaintiff is anxious about social interactions because she fears people will perceive her as sad and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to keep makeup on her face. She is aware of the concerned looks from well-intentioned friends and strangers who perceive her to be emotional and upset.

53. Due to the nasolacrimal duct obstruction Plaintiff feels as though most daily activities are more trouble than they are worth. Plaintiff has difficulty watching television, driving, and reading as a result of the tearing. In particular, reading has become so difficult that Plaintiff needs a line marker and magnifying glass. The only

time that Plaintiff does not feel discomfort from the tearing is when her eyes are shut. Simply put, Plaintiff's tearing has negatively impacted her whole way of life.

54. Plaintiff has undergone multiple surgeries to repair her lacrimal system and alleviate the persistent epiphora. Nevertheless, Plaintiff continues to suffer from painful and debilitating tearing.

55. Plaintiff's injuries could have been prevented had Defendants simply warned that permanent nasolacrimal duct obstruction is a common but preventable side effect of Docetaxel Injection concentrate. Specifically, had Defendants properly warned Plaintiff's oncologist of the rapid onset of permanent damage, her oncologist would have advised her to inform him immediately at the onset of her symptoms and referred her to the appropriate lacrimal specialist. Plaintiff thus seeks recovery for her mental and physical suffering stemming from permanent, but easily preventable, lacrimal duct obstruction.

VII. Tolling of the Statue of Limitations

56. Alternatively, Plaintiff files this lawsuit within the applicable statute of limitations period of first suspecting that Defendants' wrongful conduct caused the appreciable harm she sustained.

57. Due to Defendants' fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Plaintiff could not, by the exercise of reasonable diligence, have discovered that Defendants wrongfully caused her

injuries since she was unaware of the severity and permanency of her injury.

58. Specifically in its warning label, which Defendants intended for oncologists to read and rely on, Defendants fraudulently concealed (1) the rapid onset at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

59. As a result, Plaintiff was unaware that Defendants knew of the devastating and permanent consequences of stenosis, or that Defendants concealed this information from her oncologist. Because Plaintiff's oncologist was unaware of the permanent nature of this side effect, Plaintiff was also unaware that her condition was **permanent**.

60. Defendants to this day do not warn that Docetaxel Injection can cause **permanent** obstruction of the lacrimal system. Therefore Plaintiff did not suspect, nor did she have reason to suspect, that she had been permanently injured. Furthermore, Plaintiff did not and could not suspect the tortious nature of the conduct causing her injuries until a date before filing this action that is less than the applicable limitations period for filing suit.

61. Upon presentation of tearing, Plaintiff was advised that tearing was a common side effect of chemotherapy that, like most other side effects of chemotherapy, would resolve. Following completion of chemotherapy treatment, Plaintiff advised her oncologist of persistent epiphora. Subsequently Plaintiff was referred to an ophthalmologist who diagnosed her with bilateral nasolacrimal duct obstruction.

62. Plaintiff first became aware that the manufacturers of Taxotere and Docetaxel Injection Concentrate knew that their chemotherapy drug could cause permanent damage to the lacrimal system after seeing a blog post on the website of the law firm of Hotze Runkle, PLLC.

63. When Plaintiff read that Defendants hid the risk of **permanent** canalicular stenosis from doctors and their patients, only then did she discover that the manufacturers of Taxotere were aware of this permanent side effect, but they intentionally withheld this information from healthcare practitioners and consumers.

64. Plaintiff could not have discovered Defendants' wrongdoing earlier, because to this date, Defendants' warning fails to fully advise of the nature of the injury, resulting in oncologists and their patients remaining in the dark. Plaintiff was only able to discover that her tearing was never going to go away after Hotze Runkle published these facts on the internet.

65. Additionally, Plaintiff was prevented from discovering this information at an earlier date because Defendants: (1) misrepresented to the public, the FDA, and the medical profession the **permanent** nature of "lacrimal duct obstruction;" (2) failed to disclose to the public, the FDA, and the medical profession its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the public, the FDA, and the medical profession its knowledge that these side effects were preventable with early intervention during chemotherapy; (4) fraudulently concealed facts and information that

could have led Plaintiff to discover Defendants' liability; and (5) still has not disclosed to the public, the FDA, and the medical profession that Docetaxel Injection concentrate can cause permanent punctal, canalicular and nasolacrimal duct stenosis which can be prevented with early intervention during chemotherapy.

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

66. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

67. At all relevant times, Defendants were in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Docetaxel Injection used by Plaintiff.

68. The Docetaxel Injection designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants failed to provide adequate warnings to users and their healthcare providers, including Plaintiff and her healthcare providers, of the risk of side effects associated with the use of Docetaxel Injection, particularly the risk of developing disfiguring, permanent nasolacrimal duct obstruction, or the measures that could have been taken to prevent it. The Docetaxel Injection designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Defendants and ultimately administered to Plaintiff lacked such warnings when it left Defendants' control.

69. The risks of developing disfiguring, permanent nasolacrimal duct obstruction were

known to or reasonably knowable by Defendants at the time the Docetaxel Injection left Defendants' control.

70. A reasonably prudent company in the same or similar circumstances would have provided a warning that communicated the dangers and safe use of Docetaxel Injection.

71. Any warnings actually provided by Defendants did not sufficiently and/or accurately reflect the symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing disfiguring, permanent nasolacrimal duct obstruction or how it could have been prevented during administration of the chemotherapy.

72. Without adequate warning of these side effects, Docetaxel Injection is not reasonably fit, suitable, or safe for its reasonably anticipated or intended purposes.

73. Plaintiff was a reasonably foreseeable user of Docetaxel Injection who used the drug in a reasonably anticipated manner.

74. Plaintiff would have taken preventative measures during the course of her chemotherapy to prevent nasolacrimal duct obstruction had she (and her physicians) been provided an adequate warning by Defendants of the risk of these side effects.

75. As a direct and proximate result of Defendants' failure to warn of the potentially severe adverse effects of Docetaxel Injection, Plaintiff suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses,

including, but not limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement, including nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT II – STRICT PRODUCTS LIABILITY (MISREPRESENTATION)

76. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

77. Defendants sold the Docetaxel Injection that Plaintiff's healthcare providers prescribed for Plaintiff and that Plaintiff used.

78. Defendants were engaged in the business of selling the Docetaxel Injection for resale, use, or consumption.

79. Defendants misrepresented facts as set forth herein concerning the character or quality of the Docetaxel Injection that would be material to potential prescribers and purchasers or users of the product.

80. Defendants' misrepresentations were made to potential prescribers and/or purchasers or users as members of the public at large.

81. As purchasers or users, Plaintiff and/or her healthcare providers reasonably relied on the misrepresentations.

82. Plaintiff was a person who would reasonably be expected to use, consume, or be affected by the Docetaxel Injection.

83. As a direct and proximate result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT III – NEGLIGENCE

84. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

85. Defendants had a duty to exercise reasonable care in the design, research, formulation, manufacture, production, marketing, testing, supply, promotion,

packaging, sale, and/or distribution of Docetaxel Injection, including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and dangerous side effects.

86. Defendants breached these duties when they put Docetaxel Injection into interstate commerce, unreasonably and without adequate and/or proper warning to Plaintiff and her healthcare providers, a product that Defendants knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

87. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to, the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Docetaxel Injection without thoroughly, adequately, and/or sufficiently testing it — including pre-clinical and clinical testing and post-marketing surveillance — for safety and fitness for use and/or its dangers and risks;

(b) Marketing Docetaxel Injection to Plaintiff, her healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent nasolacrimal duct obstruction;

(c) Marketing Docetaxel Injection to the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Docetaxel Injection;

(d) Advertising and recommending the use of Docetaxel Injection without sufficient knowledge of its safety profile;

(e) Designing, manufacturing, producing, and/or assembling Docetaxel Injection in a manner that was dangerous to its users;

(f) Concealing information from Plaintiff, her healthcare providers, the public, other medical and healthcare professionals, and the FDA that Docetaxel Injection was unsafe, dangerous, and/or non-conforming with FDA regulations;

(g) Concealing from and/or misrepresenting information to Plaintiff, her healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Docetaxel Injection; and

(h) Encouraging the sale of Docetaxel Injection, either directly or indirectly, orally or in writing, to Plaintiff and her healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects such as punctal, canalicular and nasolacrimal duct stenosis.

88. Despite the fact that Defendants knew or should have known that Docetaxel Injection caused unreasonably dangerous side effects, Defendants continues to market, manufacture, distribute, and/or sell Docetaxel Injection to consumers.

89. Plaintiff and her healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of Docetaxel Injection and measures that could have been taken to prevent severe and permanent disfigurement from the use of Docetaxel Injection.

90. Defendants knew or should have known that consumers such as Plaintiff would use its product and would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care, as set forth above.

91. Defendants' negligence was a proximate cause of Plaintiff's injuries, harms, damages, and losses, in connection with the use of Docetaxel Injection, including but not

limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement including permanent nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT IV – NEGLIGENT MISREPRESENTATION

92. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

93. Defendants had a duty to represent to Plaintiff, her healthcare providers, the healthcare community, and the public in general that Docetaxel Injection had been tested and found to be safe and effective for the treatment of various forms of cancer.

94. When warning of safety and risks of Docetaxel Injection, Defendants negligently represented to Plaintiff, her healthcare providers, the healthcare community, and the public in general that Docetaxel Injection had been tested and was found to be safe and/or effective for its indicated use.

95. Defendants concealed their knowledge of Docetaxel Injection defects from Plaintiff, her healthcare providers, and the public in general and/or the healthcare community

specifically.

96. Defendants concealed this information with the intent of defrauding and deceiving Plaintiff, her healthcare providers, the public in general, and the healthcare community in particular, and were made with the intent of inducing Plaintiff, her healthcare providers, the public in general, and the healthcare community in particular, to recommend, dispense, and/or purchase Docetaxel Injection.

97. Defendants failed to exercise ordinary and reasonable care in its representations of Docetaxel Injection in its sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, and Defendants negligently misrepresented Docetaxel Injection's high risks of unreasonable, dangerous side effects. These side effects were unreasonable because they could have been entirely prevented with adequate warning.

98. Defendants breached their duty in misrepresenting Docetaxel Injection's serious side effects to Plaintiff, her healthcare providers, the healthcare community, the FDA, and the public in general.

99. Plaintiff and her healthcare providers reasonably relied on Defendants to fulfill their obligations to disclose all facts within their knowledge regarding the serious side effects of Docetaxel Injection and the ability to prevent those side effects with appropriate precautionary measures.

100. As a direct and proximate result of the foregoing acts and omissions, Defendants

caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests that judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT V – FRAUDULENT MISREPRESENTATION

101. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

102. In its labeling information, Defendants communicated to Plaintiff, her healthcare providers, the healthcare community, and the public in general that "excessive tearing which may be attributable to lacrimal duct obstruction has been reported" and that excessive tearing is a common side effect. These statements misrepresented the true risk of harm to patients, in that they failed to fully inform oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially **permanent** nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the

condition is highly preventable with timely intervention during chemotherapy.

103. Despite having knowledge of this side effect, Defendants fraudulently omitted from this vague warning of "lacrimal duct obstruction" and/or "excessive tearing" that Docetaxel Injection could and did cause **permanent** damage to the lacrimal system, including canalicular stenosis.

104. These representations were material and false.

105. Defendants made these representations and omissions:

(a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or belief of falsity of the resulting statements;

(b) positively and recklessly without knowledge of their truth or falsity;

(c) with knowledge that they were made without any basis; and/or

(d) without confidence in the accuracy of the representations or statements resulting from the omissions.

106. Defendants made these false representations with the intention or expectation that Plaintiff, her healthcare providers, the public in general, and the healthcare community in particular, would recommend, dispense, and/or purchase Docetaxel Injection, all of which evidenced a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Plaintiff.

107. At the time Defendants made the aforesaid representations, and, at the time Plaintiff used Docetaxel Injection, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of Defendants' representations, statements and/or implications and

justifiably and reasonably relied on Defendants' representations, statements, and implications, believing them to be true.

108. In reliance on Defendants' representations, Plaintiff and her healthcare providers were induced to and did use and prescribe Docetaxel Injection, which caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT VI – FRAUDULENT CONCEALMENT

109. Plaintiff incorporates by reference the above paragraphs as if set forth herein.

110. At all times during the course of dealing between Defendants and Plaintiff and her healthcare providers, Defendants misrepresented the design characteristic and safety of Docetaxel Injection for its intended use.

111. Defendants knew or were reckless in not knowing that their representations were false due to Defendants' access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal system caused by Docetaxel Injection. In representations made to Plaintiff and her healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

112. Defendants had a duty to disclose to Plaintiff and her healthcare providers the defective nature of Docetaxel Injection, including, but not limited to, the heightened risks of disfiguring, permanent nasolacrimal duct obstruction.

113. Defendants had a duty to disclose to Plaintiff and her healthcare providers that the disfiguring, permanent nasolacrimal duct obstruction caused by the use of Docetaxel Injection could have been prevented by early identification and treatment of epiphora during chemotherapy.

114. Defendants had sole access to material facts concerning the defective nature of Docetaxel Injection and its propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used the drugs at issue, including Plaintiff.

115. Defendants' concealment and omissions of material fact concerning the safety of Docetaxel Injection were made purposefully, willfully, wantonly, and/or recklessly to

mislead Plaintiff and her healthcare providers into reliance on the continued use of the drug and to cause them to purchase, prescribe, and/or dispense Docetaxel Injection and/or use it.

116. Defendants knew that Plaintiff and her healthcare providers had no way to determine the truth behind their concealment and omissions, including the material omissions of fact surrounding Docetaxel Injection set forth herein.

117. Plaintiff and her healthcare providers reasonably relied on information disclosed by Defendants that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

118. As a result of the foregoing acts and omissions, Defendants caused Plaintiff to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future medical expenses; past and future loss and impairment of earning capacity; permanent disfigurement, including permanent nasolacrimal duct obstruction; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Plaintiff respectfully requests judgment in her favor and against Defendants in an amount that exceeds $75,000, plus the costs of this suit and any other

and further relief this Court deems just and proper.

WHEREFORE, Plaintiff respectfully requests that this Honorable Court enter judgment in favor of Plaintiff and against Defendants in an amount which exceeds $50,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

Respectfully submitted,

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